DEPARTMENT OF HEALTH & HUMAN SERVICES

94984d

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

July 29, 2004

Ref: 2004-DAL-WL-27

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James W. Jacobs, Owner
Jacobs Ranch L.L.C
Route 2, Box 86
Sulphur, Oklahoma 73086

Dear Mr. Jacobs:

An investigation performed by the U.S. Food and Drug Administration (FDA) included visits to your cattle operation located at Route 2, Box 86, Sulphur, Oklahoma on March 11, 2004. The investigation confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On November 6, 2003, you sold a cow, identified with a back tag number [redacted] at [redacted] The cow was purchased by a buyer and offered for slaughter as human food on November 7, 2003 at [redacted] USDA Establishment Number [redacted] USDA analysis (Laboratory Report # 00433655) of tissue samples collected from that animal identified the presence of 0.1 ppm and 0.26 ppm of penicillin in the kidney and the liver tissues, respectively. A tolerance of 0.05 parts-per-million (ppm) has been established for residues of penicillin in the uncooked edible tissues of cattle (Title 21, Code of Federal Regulations, Section 556.510). The presence of this drug in the edible tissues of this animal at the reported levels causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." As it applies to this case, "insanitary conditions" means that you hold animals under conditions that may allow medicated animals bearing potentially harmful drug residues to enter the food supply.

For example, our investigators noted the following conditions on your farm.

1. Failure to maintain a control system to ensure that animal drugs are used properly. Specifically, no medical treatment records are maintained. No temporary or permanent record-keeping systems are in place to identify treated animals, the dates of treatment, the drug(s) administered, who administered the drug(s), the amount administered, route of administration, and the withdrawal time to be observed prior to slaughter or sale of the animals.

2. Failure to maintain a system for identifying and tracking the purchase and sale of medicated animals. Specifically, there is no system to identify medicated animals at the time of purchase or at the time of sale to ensure that the animal is withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues of animals before being slaughtered for human consumption.

Food from animals held under such conditions is adulterated. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Edwin Ramos, Compliance Officer at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

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